UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/479,877	01/10/2000	MARCIA K. WOLF		3642

7590 02/26/2003

Elizabeth Arwine Patent Attorney
U S Army Medical Research & Materiel Command
504 Scott Street
Fort Detrick, MD 21702-5021

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/479,877	Wolf
Examiner	**Art Unit**
Portner	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 25, 2002*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *4-7 and 14-16* is/are pending in the application.

4a) Of the above, claim(s) *4 and 5* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *6, 7, and 14-16* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *4-7 and 14-16* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 4-7 and 14-17 are pending.

Claims 6-7, 14-17 are elected and under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejection Withdrawn

2. The disclosure objected to because of the following informalities: At page 23, of the specification, SEQ #6 is shown and designated to have 146 amino acids. What is shown is a sequence with 167 amino acids, not 146, in light of the amendment correcting the numbering for the shown sequence.
3. Claims 6 and 14 rejected under 35 U.S.C. 101, in light of the claims having been amended to recite an isolated and purified protein or polypeptide and no longer read on a product of nature.
4. Claims 7 and 15 rejected under 35 U.S.C. 101, in light of the claims having been amended to recite an isolated and purified protein or polypeptide and no longer read on a product of nature.

Rejections Maintained

5. Claims 6-7 and 17 (vaccine claim dependent upon claims 6-7) and claims 14-16 (claim 16 being a vaccine claim dependent upon claims 14 and 15) rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of protein and peptides that can be formulated into immunogenic compositions for the stimulation of an immune response, does not reasonably provide enablement for the utilization of any peptide fragment of a protein that shares homology (at least 60% with SEQ ID No 10), or any CS6:CssB subunit for induction of a protective immune response. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for reasons of record in paper # 14, paragraph 10.
6. Claims 14-16 rejected under 35 U.S.C. 112, first paragraph *(written description)* , as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention (scope) , for reasons of record in paper number 14, paragraph 11.

7. Claims 14-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, , for reasons of record in paper number 14, paragraph 12.

8. Claims 6-7, 17 and 14-16 rejected under 35 U.S.C. 102(b) as being anticipated by McConnell et al (1988), , for reasons of record in paper number 14, paragraph 14.

9. Claims 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Willshaw et al (reference disclosed in instant specification, page 2, paragraph 5, FEMS Microbiology Letters, vol. 49, pages 473-478, 1988, see seq.align.), , for reasons of record in paper number 14, paragraph 15.

Response to Arguments

10. The rejection of claims 6-7 and 14-17 under 35 U.S.C. 112, first paragraph (scope), because the specification, while being enabling for the production of protein and peptides that can be formulated into immunogenic compositions for the stimulation of an immune response, does not reasonably provide enablement for the utilization of any peptide fragment of a protein that shares homology (at least 60% with SEQ ID No 10), or any CS6:CssB subunit for induction of a protective immune response. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims is traversed on the grounds that the claimed invention was "non-enabled" and "administration of the antigen to stimulate production of mucosal antibodies via the methods disclosed in the application is well known to those of skill in the art".

11. It is the position of the examiner that the scope of enablement rejection could be obviated by canceling claims 16 and 17 which are directed to compositions that require the components to

induce a protective immune response to prevent infection and disease or treat pre-existing disease. The scope of the claims is enabled for immunogenic compositions, but not vaccines.

Applicant's arguments directed to induction of a mucosal immune response is not commensurate in scope with the instantly claimed invention which must not only induce an immune response, but a protective immune response. Amendment of claims 16 and 17 to recite claim limitations --Compositions for induction of a mucosal immune response-- or an equivalent phrase, could obviate this rejection. The rejection is maintained for reasons of record.

12. The rejection of claims 14-16 under 35 U.S.C. 112, first paragraph *(written description)*, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (scope) is traversed on the grounds that the rejection asserted that the claimed invention is "non-enabled".

13. It is the position of the examiner that while written description is the basis for enablement, the rejection was made under 35 U.S.C. 112, first paragraph written description, which requires that the claimed subject matter be described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Clearly the instant specification describes SEQ ID Nos 10 thus enabling this species of the claimed genus.

14. The rejection of claims 14-16 under 35 U.S.C. 112, first paragraph *(written description)*, is additionally traversed by Applicant asserting that conservative substitutions are well known at the time the application was filed.

15. It is the position of the examiner that the claimed genus of homologs set forth in claims 14-16 are not limited to only conservative substitutions.

Claim 14 recites the phrase "wherein in all instances, the substitutions are conservative", but homologs need not only evidence conservative substitutions in a specific sequence. Homologs also include deletions and additions of amino acids. Even if the claim were amended to recite that only conservative substitutions in SEQ ID No 10 would be claimed, there is no description of what or how many amino acids are in the claimed peptides that comprise additional amino acids, in addition to the sequence that shares homology with SEQ ID NO 10, nor where the conservative substitutions would be toleration to maintain immunogenicity of SEQ ID NO 10.

The specification proposes to discover other members of the genus by using sequence homologies and introduction of alterations based upon what is already known. There is no description, however, of what these alterations are structurally. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

16. Applicant states that the last paragraph on page 8 is "not understood"

17. For illustrative purposes only, the following diagram is being provided to show the claimed invention of claim 14 which is directed to homologs of SEQ ID NO 10 with at least 60% sequence identity.

C=conservative substitution; ---- = reference sequence; ^^^ = deletion or additional sequence

Reference SEQ ID NO: ---------- (146 amino acids)

Homolog of SEQ: --------^---^---^----^-------- (126 amino acids with deletions of 20 amino acids in any location; new epitopes are created that are not present in the parent sequence, which have not been described)

Homolog of SEQ: ^^^-------^^^^^---------^^^^---------- (204 amino acids: 146 common amino acids with 58 additional/insertional amino acids; which may or may not be conservative)

Homolog with both substitutions and additions:----CCCC---^-------^----------^-------(170 amino acids, 19 being conservative amino acids, 15 amino acids being added)

The final homolog sequences sharing at least 60 % homology with the reference sequence. Polypeptides with changes in any location, of any type of change, and may evidence any function have not been described. The rejection is maintained for reason of record.

18. The rejection of claims 14-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention was not traversed; the rejection is maintained for reasons of record.

19. The rejection of claims 6-7, 17 and 14-16 under 35 U.S.C. 102(b) as being anticipated by McConnell et al (1988); and claims 14-16 under 35 U.S.C. 102(b) as being anticipated by Willshaw et al (reference disclosed in instant specification, page 2, paragraph 5, FEMS Microbiology Letters, vol. 49, pages 473-478, 1988, see seq.align) are traversed on the grounds that "The instant application relates to a particular part of a protein that must be present in a vaccine to provide adequate protection for patient to be protected" and the instantly claimed invention defines over the prior art by the "identification of a peptide sequence which is necessary to provide protection."

20. It is the position of the examiner that all of the claims recite the term "protein" or "polypeptide" and no longer recite the term "peptide" as argued. Even so, the claims are directed to compositions that comprise the recited sequence which read on the native protein. None of the claims are directed to methods of utilizing a peptide for induction of a protective immune response; a method is a new use for a known product. Applicant's arguments directed to methods of inducing a protective immune response are not commensurate in scope with the instantly elected, claimed invention. Identification of a new characteristic of an old product or composition does not make the product patentable. Atlas Powder Co. V IRECA, 51 USPQ2d

1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

The prior art rejections are maintained for reasons of record in paper number 14.

21. Applicant asks "Is the examiner requesting a Declaration?"

22. The examiner at no time requested a Declaration.

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242. /J John Doll - Chambers -

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
February 20, 2003

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600